UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

) MDL No. 1456
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) CIVIL ACTION: 01-CV-12257-PBS
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) Judge Patti B. Saris
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TRACK 1 DEFENDANTS' OPPOSITION TO PLAINTIFFS' PROPOSED ADDITION OF CLASS REPRESENTATIVES AND PROPOSED CONSOLIDATED ORDER RE: MOTION FOR CLASS CERTIFICATION

INTRODUCTION

Plaintiffs' response to the Court's August 16, 2005 decision and order demonstrates that they have no adequate class representatives for any of the three classes the Court indicated it would certify.

The Court provided plaintiffs 60 days to file an amended complaint naming individual Medicare Part B beneficiaries who could serve as Class 1 representatives, simultaneously produce documentation showing that these individuals made payments based on AWP for Part B physician-administered drugs ("PADs") manufactured by the Track 1 defendants, and file a proposed class certification order "consistent with this decision." In re Pharm. Indust. Average Wholesale Price Litig., 230 F.R.D. 61, 81, 96 (D. Mass. 2005) ("Class Cert. Decision"). When plaintiffs filed their Third Amended Master Consolidated Complaint ("TAMCC") on October 17, 2005, they named no individuals who can establish that they are Class 1 representatives and produced no documents showing that any of the proposed representatives made payments for PADs on the basis of AWP. Indeed, many of the documents that have been produced and the depositions taken by defendants affirmatively demonstrate that these individuals are not adequate Class 1 representatives. Plaintiffs have forfeited their opportunity to join Class 1 representatives. Having led the Court to believe that they had "identified individuals who could serve as additional class representatives" who were "waiting in the wings," Class Cert. Decision at 80, 81, plaintiffs have failed to come up with any suitable Class 1 representatives. After nearly four years of litigation, enough is enough. The Court should refuse to certify Class 1.

Without authorization from the Court, plaintiffs also added in their TAMCC two new benefit funds as Class 2 representatives and one of the new benefit fund and 23 new

individuals as Class 3 representatives. However, none of these parties nor any of the existing parties can represent the statewide Massachusetts classes the Court authorized because none of them has any connection with Massachusetts and therefore cannot make a claim under Massachusetts law. The discovery taken to date has also demonstrated numerous reasons why these parties are inadequate class representatives in addition to their lack of any connection with Massachusetts. Accordingly, the Court should decertify Classes 2 and 3.1

I. PLAINTIFFS HAVE FAILED TO IDENTIFY AN ADEQUATE CLASS 1 REPRESENTATIVE.

The Court ordered proposed class representatives for Class 1 to allege facts demonstrating adequacy and typicality and to "disclose the documents demonstrating that the proposed class representatives made co-insurance payments (at least in part) under Medicare Part B based on AWP." *Class Cert. Decision*, 230 F.R.D. at 81. Plaintiffs have failed to satisfy the Court's directive and meet their burden to demonstrate the adequacy and typicality of the newly proposed Class 1 representatives.

Of the 31 individuals and entities proposed as Class 1 representatives in plaintiffs' Proposed Order, only six are actually Medicare Part B beneficiaries. None of these beneficiaries has produced documents establishing that he or she made co-insurance payments under Medicare Part B based on AWP for a physician-administered drug manufactured by a

Plaintiffs' Proposed Order also seeks to certify classes pursuant to Rule 23(b)(2), even though plaintiffs did not seek – nor did the Court grant – certification under that provision. In addition, plaintiffs audaciously attempt to amend the Court's August 16th decision by incorporating it in the Proposed Order "[t]o the extent that [the August 16th decision] is not inconsistent herewith." Exh. 1, Plaintiff's Proposed Order at 7.

These individuals are identified in paragraphs 14-21 of the TAMCC. The Estate of William Newell withdrew as a plaintiff on November 29, 2005. *See* Exh. 2, Letter from Donald Haviland to Kristi Prinzo (Nov. 29, 2005).

Track 1 defendant.³ In addition, these representatives are so utterly lacking in understanding regarding the nature of the claims at issue that they cannot possibly fulfill their obligations as class representatives under Rule 23. Inexplicably, plaintiffs also propose entities and individuals that are not Medicare Part B beneficiaries as "alternative" Class 1 representatives. *See* Exh. 1, Plaintiffs' Proposed Order at 2. This attempt to add plaintiffs that are not even members of the Class they seek to represent should be summarily rejected. Accordingly, no Medicare Part B beneficiary class can be certified.

A. Plaintiffs Have Failed To Demonstrate That They Are Members Of Class 1.

Although plaintiffs have identified six individual Medicare Part B beneficiaries as representatives for Class 1, they have failed to meet their burden to produce documents "demonstrating that the proposed class representatives made co-insurance payments (at least in part) based on AWP" for the Part B drugs at issue in the TAMCC for each Track 1 defendant. Class Cert. Decision, 230 F.R.D. at 81. Not all Medicare beneficiaries actually pay their 20% co-payments. Indeed, the Court recognized that approximately 85% of all Medicare beneficiaries (as of 2000) had Medigap insurance "which pays all or some of this 20% co-payment." Class Cert. Decision, 230 F.R.D. at 71. Every proposed Class 1 representative has supplemental insurance. See TAMCC ¶¶ 15-20. Since 1992, all federally regulated Medigap

³ Plaintiffs' inadequate and incomplete document production is documented in the Declaration of Ronald G. Dove, Jr., filed herewith.

One proposed Class 1 representative – Leroy Townsend – is not alleged in the complaint to have supplemental insurance, *see* TAMCC ¶ 14, but he acknowledged at his deposition that he had such insurance. (Exh. 3, Townsend Rough Dep. at 21-22.)

policies have covered the entire 20% co-payment.⁵ Other supplemental insurance policies – for example, those provided as a retirement benefit – can cover all of the beneficiary's Medicare co-payments or they can require the beneficiary to make either a flat co-payment or a percentage co-payment.⁶ Beneficiaries with supplemental insurance that covers all of their 20% co-payment or requires a flat co-payment are not members of Class 1. Indeed, the Court defined a typical Part B consumer as one who "pays a percentage of AWP as a co-pay." *Class Cert. Decision*, 230 F.R.D. at 82.

As summarized below, plaintiffs have produced no evidence that any of the six proposed Class 1 representatives made such payments. In addition, plaintiffs have flatly refused to produce documents showing whether the proposed representatives had Medigap or other supplemental insurance that prevents them from being a class representative. Typical of plaintiffs' stonewalling on this critical issue is the letter written by one class counsel with respect to one of the proposed Class 1 representatives:

Whether Mr. Townsend had any type of supplemental insurance, and what that insurance might have paid for, is simply irrelevant. Mr. Townsend has presented clear, uncontroverted evidence that he paid for at least six of his Zoladex injections based on AWP, as a Medicare beneficiary. Thus, plaintiffs will not produce documents relating to any supplemental insurance Mr. Townsend may have had.⁷

See Exh. 4, Choosing a Medigap Policy: A Guide to Health Insurance for People With Medicare 17, 43-44 (2005), available at http://www.medicare.gov/Library/PDFNavigation/PDFInterim.asp?Language=English&Type=PubID=02110.

⁶ See Exh. 5, Declaration of Steven J. Young in Opposition to the Plaintiffs' Motion for Class Certification, ¶¶ 175-81 (Oct. 25, 2004).

Exh. 6, Letter from John A. Macoretta to James J. Duffy (Nov. 21, 2005); see also Exh. 7, Letter from Scott Berman to D. Scott Wise (Oct. 26, 2005); Dove Decl. ¶¶ 5, 19 and 24.

1. Susan Aaronson

Mrs. Aaronson is alleged to have made payments based on AWP for GSK's Ventolin (albuterol sulfate) and Zofran (odansetron), Ortho Biotech's Procrit (epoetin alpha), and BMS's Paraplatin (carboplatin injectible) and Taxol (paclitaxel). (TAMCC ¶ 15.)⁸ However, Mrs. Aaronson's husband, who was deposed in his wife's stead, testified that *all* of Mrs. Aaronson's treatments were received in the hospital and covered under Medicare Part A, not Medicare Part B. (Exh. 8, Aaronson Dep. at 32-33; 37-38.) Furthermore, according to the Medicare documents produced by plaintiffs, the only drugs for which Mrs. Aaronson "may" have been billed are carboplatin and paclitaxel. (Exh. 9, AARON 0046-152.) Generic versions are available for both of these drugs. Although BMS manufactures the brand version, plaintiffs have produced no evidence indicating which manufacturers' version of these drugs (or any of the drugs administered to Mrs. Aaronson) were used. Finally, there is no evidence that Mrs. Aaronson was even administered Ventolin, Zofran or Procrit, as alleged in the TAMCC.

2. James Shepley

Mr. Shepley is alleged to have made payments based on AWP for AstraZeneca's Zoladex (goserelin acetate implant) and Ortho Biotech's Procrit (epoetin alpha). (TAMCC ¶ 18.) However, plaintiffs have failed to produce a single document reflecting that Mr. Shepley was charged anything at all for Zoladex or Procrit, much less that any charges were based on AWP.

The TAMCC (¶¶ 14-21) lists a multitude of drugs taken by the six Medicare beneficiaries proposed as class representatives. However, only a limited number of these drugs are both manufactured by the Track 1 defendants and listed by plaintiffs as a "Subject Drug." See Exh. 1, Attachment to Plaintiff's Proposed Order. Only the limited number of subject drugs allegedly taken by the proposed representative are identified in the text.

Indeed, Mr. Shepley could not recall making any payments for Zoladex or Procrit. (Exh. 10, Shepley Dep. at 79.)

3. Robert Howe

Mr. Howe is alleged to have made payments based on AWP for AstraZeneca's Zoladex (goserelin acetate implant) and GSK's Kytril (granisetron). (TAMCC ¶ 17.) Neither the documents produced nor Mr. Howe's testimony establish that he made any payments for these drugs based on AWP. Although plaintiffs produced certain of Mr. Howe's cancelled checks, the amounts reflected on those checks do not correspond with charges contained in any billing statement or document produced to defendants. As Mr. Howe acknowledged during his deposition, it is impossible to determine from the documents produced whether, how much, and on what basis, he actually paid for any of the subject drugs. (Exh. 11, Howe Dep. at 192-93.) Moreover, even assuming he could establish that he made co-payments based on AWP, Mr. Howe's claims would not be typical of any Zoladex or Kytril class. Mr. Howe testified that he first took Zoladex in June 2003 (id. at 207), approximately one and a half years after the original complaint was filed in the case. Accordingly, Mr. Howe would be subject to unique defenses not necessarily available against the class of Zoladex users as a whole. With respect to GSK, the two documents produced by Mr. Howe referring to Kytril are from 2005. (Exh. 12, HOWE 0051, four unstamped pages.) Because GSK sold Kytril to Hoffmann-La Roche in December 2000, see TAMCC ¶ 418, Mr. Howe cannot represent a class of Kytril users who seek to sue GSK.

4. Estate of Patricia Young

Mrs. Young is alleged to have made payments based on AWP for BMS's Cytoxan (cyclophosphamide) and Coumadin (warfarin sodium injectible), Ortho Biotech's Procrit

(epoetin alpha), and Centocor's Remicade (infliximab). (TAMCC ¶ 19.) The documents produced show that she was given Cytoxan by her oncologist to treat lymphoma and later warfarin sodium tablets, which are taken orally and are not on the list of subject drugs. There is no evidence that Mrs. Young made any payments for any of these BMS drugs, or that she was ever administered the injectible form of warfarin sodium. In fact, Mr. Young testified that he and his wife never paid anything to the oncologist or to the hospital where she was given the warfarin tablets. The drugs were fully covered by either Medicare Part B or his supplemental insurance. (Exh. 13, Young Dep. at 149, 161-166.) Although there is evidence of some payments for Centocor's Remicade, these payments were not percentage co-insurance payments based on AWP. Rather, Mrs. Young's payments to her rheumatologist for drug infusions were payments toward her supplemental-insurance deductible unrelated to AWP that she had arranged with a bookkeeper at the clinic. (see id. at 84-85). In addition, even if Mrs. Young's payments were based on AWP, her claims would not be typical of the class. The documents indicate that she first took Remicade in 2002, and that she first took Cytoxan and Procrit as recently as September and October 2004, well after the complaint in this case was filed. (Exh. 14, YOUNG 0085, 0098, 0099-0101.) Accordingly, she is subject to unique defenses not necessarily applicable to the rest of the class.

5. David Clark

Mr. Clark is alleged to have made payments based on AWP for GSK's Kytril (granisetron) and Ortho Biotech's Procrit (epoetin alpha). (TAMCC ¶ 16.) Mr. Clark passed away on November 5, 2005, before he could be deposed. Although plaintiffs have indicated that they plan to substitute his estate and make his son available for deposition, they failed to do so before the discovery cut-off. *See* Exh. 15, Letter from TerriAnne Benedetto to Mark Young

(Nov. 23, 2005). Accordingly, Mr. Clark should be stricken as a class representative. In any event, the documents produced on Mr. Clark's behalf do not appear to indicate any payments based on AWP. Furthermore, Mr. Clark is conceded to have had supplemental insurance coverage (*see* TAMCC ¶ 16), but no documents describing the terms of that coverage have been produced. Without documentation establishing the terms of his supplemental insurance, plaintiffs have not demonstrated that Mr. Clark made co-insurance payments under Medicare Part B based on AWP.

6. Leroy Townsend

Mr. Townsend is alleged to have made payments based on AWP for

AstraZeneca's Zoladex (goserelin acetate implant). (TAMCC ¶ 14.) Although it appears that on
a number of occasions Mr. Townsend paid money in connection with his Zoladex injections, Mr.
Townsend also testified that – from 1991 to the present – he was covered under a supplemental
health insurance policy with either Aetna or United Healthcare, which were provided as a
retirement benefit by his former employers. (Exh. 3, Townsend Rough Dep. at 21-22.) As noted
above, plaintiffs' counsel has refused to produce any documents concerning Mr. Townsend's
supplemental insurance, and he could not testify as to the scope of his coverage under these
supplemental policies. Indeed, he could not explain whether or why he would be making coinsurance payments for his Zoladex injections while he had supplemental insurance. (see id. at
110-113, 124-127.) In the absence of documentation describing the terms of his supplemental
insurance, the Court cannot determine whether Mr. Townsend is a member of the class he
purports to represent.

* * *

In sum, plaintiffs have uniformly failed to demonstrate that payments made by the proposed Class 1 representatives were based upon AWP. Their refusal to produce critical information about their supplemental insurance coverage makes it impossible to determine whether the proposed representatives are even members of Class 1. As a result, the proposed Class 1 representatives have failed to demonstrate that they meet the Court's test for membership in Class 1. In the absence of appropriate representatives, no Class 1 can be certified against the Track 1 defendants.⁹

- B. The Claims Of The Class 1 Representatives Are Atypical Of The Claims Of The Class.
 - 1. There Are No Proposed Class Representatives For 25 Of The 29 Drugs Identified By Plaintiffs As Subject Drugs.

Plaintiffs have failed to propose a Class 1 representative for each of the drugs listed on the Table of Subject Drugs attached to their Proposed Order. In fact, the record shows that only 4 of the 29 subject drugs were administered to the proposed Class 1 representatives (putting aside Mrs. Aaronson, who was covered under Part A). Plaintiffs apparently take the view that a class representative who paid for one of a defendant's drugs is an adequate

If the Court is not prepared to reject these proffered Class 1 representatives on the basis of the present record, the Court should permit defendants an additional 90 days to take discovery. The 30 days allowed by the August 16 order contemplated only depositions of Class 1 representatives on the basis of a complete document production *simultaneous* with the filing of the TAMCC. *See Class Cert. Decision*, 230 F.R.D. at 96. Plaintiffs' production was not simultaneous with the filing of the TAMCC, and it still is not complete. Because plaintiffs themselves know so little about the status of their supplemental insurance, discovery from their insurers will be necessary.

AstraZeneca's Zoladex, Ortho Biotech's Procrit, Centocor's Remicade, and BMS's Cytoxan.

representative for all of the subject drugs manufactured by that defendant. (Even on that view, plaintiffs have no representative for GSK¹¹ or Schering-Plough. ¹²)

However, the claims of a Class 1 representative relating to one drug are not typical of class claims relating to other drugs manufactured by the same defendant. For example, the claims of a user of AstraZeneca's Zoladex, an injectible drug for prostrate cancer for which plaintiffs have named a proposed Class 1 representative, are not typical of the claims of users of AstraZeneca's Pulmicort, a respiratory inhalant for which no class representative has been identified. Furthermore, Zoladex has been covered by Medicare Part B since 1991, but Pulmicort only became covered by Medicare Part B in 2002, after the initial AWP complaint was filed. Similarly, the claims of a user of BMS's Cytoxan, a chemotherapy agent for which plaintiffs have named a proposed Class 1 representative, are not typical of the claims of users of BMS's Coumadin injectible, a blood-thinner for which there is no proposed Class 1 representative. Accordingly, plaintiffs cannot pursue class claims relating to the 25 drugs for which there is no proposed representative.

2. Even If The Proposed Class 1 Representatives Were Members Of The Class, They Are Not Adequate Representatives.

Even if the proposed Class 1 representatives were members of Class 1, their testimony indicates that they cannot adequately protect the interests of absent class members.

Each of the proposed Class 1 representatives who is alleged to have paid for a GSK drug is unsuitable as a class representative. All of Mrs. Aaronson's medications were covered under Part A rather than Part B; Mr. Howe took Kytril when it was no longer a GSK product; and Mr. Clark is deceased.

None of the six Medicare beneficiaries is alleged to have been administered a Schering-Plough drug that is included in plaintiffs' list of subject drugs.

Several of the proposed Class 1 representatives lack basic knowledge of the case. ¹³ In addition, several of the proposed representatives hold opinions contrary to the fundamental premises of the case, including disclaiming any interest in obtaining monetary damages. ¹⁴ Furthermore, most of the proposed Class 1 representatives have failed to produce relevant documents admittedly in their possession. ¹⁵ "One who will not comply wholeheartedly and fully with discovery requirements of modern federal requirements should not be regarded as one to whom the important fiduciary duty of acting as a class representative should be entrusted." *Norman v. Arcs Equities Corp.*, 72 F.R.D. 502, 506 (S.D.N.Y. 1976). Collectively, these deficiencies demonstrate that the proposed Class 1 representatives do not satisfy the requirements of Rule 23(a)(4).

Mr. Shepley could not identify a single defendant or even whether the defendants included doctors, pharmaceutical manufacturers, wholesalers or retail pharmacies. See Exh. 10, Shepley Dep. at 69-70. In fact, Mr. Shepley thought the litigation was about Lupron – a drug not even at issue in this case. See id. at 26-27. Similarly, Mr. Townsend could not explain why he allegedly has continued to make payments based on AWP even after he filed a complaint alleging AWP fraud. See Exh. 3, Townsend Rough Dep. at 142-43. Class certification may be properly denied where, as here, "the class representatives ha[ve] so little knowledge of and involvement in the class action that they would be unable or unwilling to protect the interests of the class against the possibly competing interests of their attorneys." Maywalt v. Parker & Parsley Petroleum Co., 67 F.3d 1072, 1077-78 (2d Cir. 1995) (quoting Kirkpatrick v. J.C. Bradford & Co., 827 F.2d 718, 727 (11th Cir. 1987)).

For example, Mr. Shepley denied that he was overcharged for Zoladex and Procrit in direct contradiction with the allegations of the complaint. See Exh. 10, Shepley Dep. at 51-52 ("Q: In this lawsuit are you claiming that you were overcharged for a drug called Procrit? A: No. Q: In this lawsuit are you claiming that you were overcharged for Zoladex? A: No. MR. HAVILAND: Do you understand her questions? Do you understand what she's asking you? THE WITNESS: Yes.")). See Rosmer v. Pfizer, Inc., No. CV 9:99-2280-18RB, 2001 U.S. Dist. LEXIS 6678, at *16 (D.S.C. Mar. 30, 2001) (plaintiff must seek the same relief as the rest of the class).

See, e.g., Exh. 11, Howe Dep. at 70-73, 191-193 (describing invoices from provider showing charges for physician-administered drugs and documents relating to supplemental insurance coverage, including plan descriptions and explanations of benefits, none of which have been produced); Exh. 3, Townsend Rough Dep. at 35-38, 105, 133-135 (same); see generally Dove Decl.

C. Plaintiffs' Attempt To Propose Non-Medicare Part B Beneficiaries As Class 1 Representatives Should Be Rejected.

The Court allowed plaintiffs to amend the complaint in order to name *individual*Medicare Part B beneficiaries as proposed representatives for Class 1. See Class Cert. Decision,
230 F.R.D. at 80-81, 96. Yet plaintiffs' Proposed Order lists third-party payors and individuals
who are not Medicare beneficiaries as Class 1 representatives. See Exh. 1, Plaintiffs' Proposed
Order at 2. The Court ruled that TPPs cannot adequately represent a class of Medicare
beneficiaries who made co-payments based on AWP. See Class Cert. Decision, 230 F.R.D. at
80-81. Accordingly, plaintiffs' proposal of these entities as Class 1 representatives should be
rejected. Plaintiffs' counsel has conceded that none of the 22 individuals listed as "alternate"
Class 1 representatives is a Medicare Part B beneficiary. Therefore, they should be rejected as
Class 1 representatives.

II. PLAINTIFFS HAVE FAILED TO IDENTIFY AN ADEQUATE CLASS 2 OR 3 REPRESENTATIVE.

In its August 16 decision and order, the Court approved two Massachusetts-only classes: TPPs that paid Medigap supplemental insurance (Class 2); and TPPs and individuals who paid for PADs on the explicit basis of AWP outside Medicare Part B (Class 3). *See Class Cert. Decision*, 230 F.R.D. at 96. Plaintiffs' Proposed Order sets forth three representatives for Class 2: United Food and Commercial Workers Unions and Employees Midwest Health Benefits Fund ("UFCW"), Pirelli Armstrong Tire Corporation Retiree Medical Benefits Trust

See Exh. 16, E-mail from Steve Berman to Mark Lynch (Nov. 14, 2005). In addition, the following record citations confirm that the alternate Class 1 representatives are not Medicare beneficiaries: Exh. 17, Barreca Dep. at 11; Exh. 18, Choice Dep. at 15; Exh. 19, Dison Dep. at 19; Exh. 20, Garcia Dep. at 26-27; Exh. 21, Kendall Dep. at 19-20; Exh. 22, Leef Dep. at 30; Exh. 23, Nelson Dep. at 14; Exh. 24, Palenica Dep. at 20; Exh. 25, Vanderwal Dep. at 62; Exh. 26, Vernick Dep. at 22; Exh. 27, Wessels Dep. at 13, 77; and Exh. 28, Hopkins Rough Dep. at 11-12.

("Pirelli"), and Sheet Metal Workers Health Fund ("SMWHF"). *See* Exh. 1, Plaintiffs' Proposed Order at 4. Plaintiffs added SMWHF and Pirelli to the TAMCC without the Court's permission or defendants' consent. For Class 3, plaintiffs propose the six benefit funds that previously have participated in this case, ¹⁷ the newly added benefit fund, SMWHF, seventeen individuals who are or were beneficiaries of UFCW and two individuals privately insured through TPPs. *See* Exh. 1, Plaintiffs' Proposed Order at 6. ¹⁸

None of the proposed Class 2 or 3 representatives should be approved because (1) neither the existing parties nor the newly-proposed representatives have sufficient contacts with Massachusetts to assert claims under Massachusetts law and therefore cannot represent parties who may have such claims; (2) no new Class 2 or 3 representatives were permitted under the Court's August 16 order, and plaintiffs have not followed the proper procedures to attempt to join these new parties; (3) as demonstrated below, the little discovery plaintiffs have permitted of the proposed Class 2 and 3 representatives establishes that they are not adequate or typical class representatives; and (4) plaintiffs' fall-back attempt to revive nationwide classes under the laws of multiple states in violation of the Court's August 16 decision should be rejected.

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United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW"); Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund ("CMHV"); Teamsters Health & Welfare Fund of Philadelphia and Vicinity ("THWF"); Philadelphia Federation of Teachers Health and Welfare Fund ("PFTHW"); Man-U Service Contract Trust Fund ("Man-U"); and Twin Cities Bakery Workers Health and Welfare Fund ("TCBW").

The TAMCC and the Proposed Order list twenty-two individual representatives, but plaintiffs have withdrawn Cynthia Byrski, Kathleen Weaver-Zech and Madolyn Vescovi as Class 3 representatives. *See* Exh. 29, Letter from Jennifer F. Connolly to H.B. Roback (Nov. 2, 2005); Exh. 30, Letter from Niraj Parekh to Allan Hoffman (Nov. 11, 2005); Exh. 31, Letter from Jennifer F. Connolly to Niraj Parekh (Nov. 16, 2005).

A. None Of The Proposed Class Representatives Has Any Contact With Massachusetts.

None of the entities proposed for Classes 2 and 3 or the individuals proposed for Class 3 has any contact with Massachusetts, and therefore none of them can adequately represent classes asserting claims under Massachusetts law.

The Court defined Classes 2 and 3 as consisting of parties asserting claims under Mass. Gen. Laws ch. 93A. *See Class Cert. Decision*, 230 F.R.D. at 96. The Court held that under applicable choice-of-law principles "the laws of the home states of the consumers govern." *Class Cert. Decision*, 230 F.R.D. at 83. Although the Court made that statement with respect to individual Medicare beneficiaries, it applies equally to TPPs. Indeed, this requirement is constitutionally mandated. *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 818 (1985) ("for a State's substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair").

None of the proposed Class 2 or 3 representatives is a resident of Massachusetts;¹⁹ none of the Track 1 defendants are residents of Massachusetts; and the proposed plaintiffs have not demonstrated that any part of their claims occurred in Massachusetts.²⁰ Indeed, after

There is precedent in the annals of AWP litigation for the principle that a non-resident entity cannot be a member of a state-specific class. The Court in *Walker v. TAP Pharmaceutical Prods., Inc.*, No. CPM-682-01, at * 2-3 (N.J. Super. Ct. Law Div., September 16, 2004), held that the certified class of "[a]ll persons and entities in New Jersey who paid any portion of the cost of Lupron" included *only* entities that maintained "an office or offices in New Jersey at the time of the sale" of the drug. *See* Exh. 32.

Although a representative of SMWHF testified that some Fund participants in the Medigap program reside in Massachusetts and that the Fund has paid reimbursement to Massachusetts-based providers (Exh. 33, Randle Dep. at 20-21), the Fund has not provided any further evidence or documentation of that fact. Plaintiffs bear the burden of demonstrating that the criteria set forth in Federal Rule of Civil (continued...)

asserting claims under Massachusetts law from the outset of this case, plaintiffs' counsel conceded on November 29, 2005, that "[n]one of the newly proposed representatives for Class 3 resides in Massachusetts nor made any payments for subject drugs in Massachusetts." Because none of the proposed class representatives can serve as an adequate representative of Massachusetts-based classes, Classes 2 and 3 cannot go forward and should be decertified.

B. The Court Did Not Authorize New Class 2 or 3 Representatives.

Pirelli, SMWHF and the proposed Class 3 individuals were named as plaintiffs for the first time in the TAMCC. The Court's August 16 order granted plaintiffs leave to file another amended complaint *only* for the narrow purpose of allowing plaintiffs to add potential individual class representatives for Class 1. If class counsel seek to propose new representatives, they must make a motion under Rules 15, 20 and 23, defendants would have an opportunity to oppose, and – if the motions are granted – the proposed entities and individuals would be subject in the first instance to at least "class" discovery (if not full merits discovery) to determine whether they met the typicality and adequacy requirements of Rule 23(a). *See* 3 Newberg on Class Actions § 7:8 (4th ed. 2005) (discovery relating to class issues). Indeed, plaintiffs have belatedly attempted to follow this course with their November 29, 2005, motion for leave to join a Massachusetts-based benefit fund. Plaintiffs should not be permitted to short-circuit the normal rules and procedures by simply adding new Class 2 and 3 representatives to the TAMCC.

Procedure 23 have been met. See, e.g., Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 613-14 (1997). And in any event, SMWHF was not timely added to this case. Furthermore, under Walker, the TPP must reside in Massachusetts. See n.19, supra.

Exh. 34, Plaintiffs' Motion for Leave to Join Pipefitters Local 537 Trust Funds As A Plaintiff and Proposed Class Representative (filed Nov. 29, 2005); see also Exh. 16, E-mail from Steve Berman to Mark Lynch (Nov. 14, 2005). Defendants will respond to plaintiffs' motion to join the Pipefitters Funds in due course.

Accordingly, plaintiffs' unauthorized addition of new plaintiffs to Classes 2 and 3 should be rejected.

C. The Limited Discovery Obtained From Plaintiffs Shows That The Newly-Proposed Class 2 And 3 Representatives Are Atypical And Inadequate.

Plaintiffs have also failed to establish that the proposed entity and individual representatives satisfy the adequacy and typicality requirements of Fed. R. Civ. P. 23(a) for additional reasons.

1. The Class 2 and 3 Entity Plaintiffs.

The productions plaintiffs have made with respect to each entity are deficient in a variety of ways. For example, the proposed Class 2 entity representatives have not produced documents sufficient to demonstrate that these entities made co-payments under Medicare Part-B based on AWP for drugs with respect to each defendant.²² In addition, with respect to generic and multi-source drugs for which these entities have allegedly made co-payments under Medicare Part B, plaintiffs have not produced any documentation sufficient to identify which manufacturer's version of the drug was used.

Based on the little discovery to date, none of the proposed Class 3 entities has established that they made payments for PADs on the basis of AWP, and they are otherwise

The documents produced by Pirelli do not indicate that it made any payments for any drug at issue in this litigation manufactured by GSK, Schering or BMS. Plaintiffs did not make Pirelli available for a deposition within the 30-day discovery period allowed by the Court. As a result, defendants did not have the opportunity to ask any questions about the documents produced and whether they in fact demonstrate that Pirelli made reimbursement payments based on AWP under Medicare Part B with respect to drugs manufactured by the other Track 1 defendants. With respect to SMWHF, plaintiffs have neither alleged that it reimbursed for any Schering-Plough or Warrick drugs, nor have they otherwise identified any Schering-Plough or Warrick drugs for which it made co-payments based on AWP under Medicare Part B. See Exh. 33, Randle Dep. at 85.

inadequate or atypical representatives of Class 3.²³ The documents that have been produced thus far show, primarily by "J Code," which drug a proposed class representative received. As the Court is aware, for multi-source drugs, a J-Code may include several brand or generic versions of a drug, each manufactured by a different defendant or even a company not a party to the case.

2. The Individual Class 3 Plaintiffs.

The individual proposed representatives generally have no idea which manufacturer's drug they received. Even in the few instances where a proposed representative may have a document (such as a billing record or an information sheet that explains the side-effects of the drug) that contains a particular manufacturer's brand name, there remains ambiguity because medical providers often use the innovator-manufacturer's name as a convenient way of describing all competing brands and generics. *See* Exh. 35, Chemocare.com, Chemotherapy Drugs, http://www.chemocare.com/bio/adriamycin.asp (last visited November 28, 2005). Thus, without more detail (such as the doctor's buying records) none of the plaintiffs can prove which manufacturer's multi-source drug they were given.

While some of the individual proposed Class 3 representatives have produced doctor's bills or other documents that show what they were charged by their physicians, few have produced documents sufficient to show that they actually paid the charges (even assuming

The 30 days allowed by the Court to depose proffered Class 1 representatives clearly is too short to take adequate discovery of the new Class 2 and 3 representatives, especially large entities like SMWHF and Pirelli.

²⁴ See, e.g., Exh. 17, Barreca Dep. at 32-33, 63; Exh. 18, Choice Dep. at 57-59; Exh. 19, Dison Dep. at 30-31; Exh. 20, Garcia Dep. at 48-49; Exh. 28, Hopkins Rough Dep. at 84-85; Exh. 21, Kendall Dep. at 59-72; Exh. 22, Leef Dep. at 53; Exh. 23, Nelson Dep. at 33, 46-47; Exh. 24, Palenica Dep. at 62-65; Exh. 26, Vernick Dep. at 31-32.

arguendo that the charges were AWP-based).²⁵ One individual – George Baker Thomson – has only produced eight pages, none of which establish that he paid for any subject drugs. *See* Exh. 36, Letter from James Duffy to TerriAnne Benedetto (Nov. 10, 2005) (Mr. Thomson has not yet been deposed because of his health.) Others, such as Mary Cauble, Regina Shoemaker, Joseph Miller and Scott Tell have not produced any documents. *See* Dove Decl. ¶¶ 49, 50, 75, 76, 90, 91, 94 and 95).

Like the proposed Class 1 representatives, the individual Class 3 representative lack sufficient knowledge of their claims and hold views that are contrary to the fundamental premises of the complaint. Most have testified in their depositions that they believed their doctors' decisions as to which drugs to prescribe were based on sound medical judgment, not improper financial incentives. Some of them do not understand that it is their physician, not the drug manufacturers, who is alleged to have benefited directly from the spread between AWP and acquisition cost of drugs. Several do not believe that there was any collusion between the doctors and the manufacturers to create "spreads." Furthermore, many of the individuals did not even start taking any of the subject drugs until after the filing of the earlier complaints in this

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²⁵ See, e.g., Exh. 18, Choice Dep. at 62-70 (Ms. Choice could not recall if she made payments for her share of the balance due providers, and testified that she is not certain whether the payments she has made were for medication or for medical services that she received).

<sup>See, e.g., Exh. 17, Barreca Dep. at 65; Exh. 18, Choice Dep. at 45-46; Exh. 19, Dison Dep. at 31;
Exh. 20, Garcia Rough Dep. at 26; Exh. 28, Hopkins Rough Dep. at 93; Exh. 21, Kendall Dep. at 51; Exh. 22, Leef Dep. at 20-21; Exh. 23, Nelson Dep. at 35-36; Exh. 24, Palenica Dep. at 73-74; Exh. 25,
Vanderwal Dep. at 18; Exh. 26, Vernick Dep. at 84-85; Exh. 27, Wessels Dep. at 28.</sup>

²⁷ See, e.g., Exh. 17, Barreca Dep. at 76-77; Exh. 24, Palenica Dep. at 36-37; Exh. 21, Kendall Dep. at 51-52; Exh. 23, Nelson Dep. at 35-36; Exh. 26, Vernick Dep. at 49-50; Exh. 27, Wessels Dep. at 109-110.

²⁸ See, e.g., Exh. 21, Kendall Dep. at 51-52; Exh. 23, Nelson Dep. at 38; Exh. 18, Vanderwal Dep. at 92-93.

case.²⁹ Because these individuals will be subject to separate defenses that they could not have been defrauded, their claims are not typical of those who took subject drugs before the complaint.

D. Plaintiffs' Unauthorized Expansion Of The Class 2 And 3 Claims Beyond Massachusetts Should Be Disregarded.

Despite the Court's unambiguous order that Classes 2 and 3 are limited to claims under Mass. Gen. Laws ch. 93A, plaintiffs seek to certify these classes under the consumer protection laws of 44 states. *See* Exh. 1, Plaintiffs' Proposed Order at pp. 4, 6; TAMCC at ¶¶ 645-49. Plaintiffs' brazen attempt to resurrect nationwide classes in violation of the Court's August 16 order should be rejected.³⁰

CONCLUSION

Plaintiffs have both exceeded and fallen short of the mandate of the Court's August 16 order. They have attempted to add more parties than the Court authorized, and they have failed to add the parties or make the showings the Court required. The proffered Class 1 representatives should be rejected because plaintiffs have not demonstrated that they made payments on the basis of AWP. The newly proffered Class 2 and 3 representatives should not be allowed because they have no connection with Massachusetts, their addition is untimely and unauthorized, and they are otherwise inadequate representatives. Plaintiffs have had more than

See, e.g., Exh. 18, Vanderwal Dep. at 15; Exh. 27, Wessels Dep. at 74-75; Exh. 37 (GMILLER 001-0024) (produced documents that show Mr. Miller taking the alleged drugs in 2004 and 2005); TAMCC ¶ 38 (Ms. Garcia only makes allegations for payments made in 2004 and 2005).

³⁰ If the Court is inclined to treat plaintiffs' maneuvers as a motion for reconsideration of the Court's August 16 order, defendants request an opportunity to file an appropriate opposition. Reargument of those matters is clearly outside the scope of the twenty-page brief the Court has authorized defendants to file on the adequacy of the proposed representatives of the classes the Court has permitted.

an ample opportunity to comply with the Court's directives, and they have failed to do so.

Accordingly, Class 1 should not be certified, and Classes 2 and 3 should be decertified for lack of a proper representative.

Respectfully Submitted,

/s/ Mark H. Lynch

Mark H. Lynch COVINGTON & BURLING 1201 Pennsylvania Avenue, N.W. Washington DC, 20004

On behalf of all Track 1 Defendants

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION)) MDL NO. 1456) CIVIL ACTION NO. 01-CV-12257-PBS
THIS DOCUMENTS RELATES TO ALL ACTIONS	Judge Patti B. Saris Chief Mag. Judge Marianne B. Bowler

SUPPLEMENTAL DECLARATION OF KRISTI T. PRINZO IN SUPPORT OF TRACK 1 DEFENDANTS' OPPOSITION TO PLAINTIFFS' PROPOSED ADDITION OF CLASS REPRESENTATIVES AND PROPOSED CONSOLIDATED ORDER RE: MOTION FOR CLASS CERTIFICATION

I, Kristi T. Prinzo, declare as follows:

- 1. I am an attorney with Davis Polk & Wardwell, counsel for defendant
 AstraZeneca Pharmaceuticals LP in this action. I submit this declaration in support of
 Track 1 Defendants' Opposition to Plaintiffs' Proposed Addition of Class
 Representatives and Proposed Consolidated Order Re: Motion for Class Certification.
- 2. Several of the exhibits submitted in support of the Track 1 Defendants'
 Opposition to Plaintiffs' Proposed Addition of Class Representatives and Proposed
 Consolidated Order Re: Motion for Class Certification contain information that has been deemed confidential and highly confidential and are hereby filed under seal.
 - 3. These include the following exhibits:

Excerpts from the rough transcript of the deposition of Leroy Townsend (Nov. 15, 2005).

EXHIBIT	<u>TAB</u>
Declaration of Steven J. Young in Opposition to the Plaintiffs' Motion for Class Certification (Oct. 25, 2004) (submitted in connection with the Track 1 Defendants' Memorandum in Opposition to Class Certification).	5
Excerpts from the transcript of the deposition of David Aaronson, testifying for Susan Aaronson (Nov. 17, 2005).	8
Excerpts from the document production of Susan Aaronson, with Bates Numbers AARON 0046-0152.	9
Excerpts from the document production of Robert A. Howe, with Bates Number HOWE 0051 & unstamped pages.	12
Excerpts from the transcript of the deposition of Larry Young, testifying for the Estate of Patricia Young (Nov. 9, 2005).	13
Excerpts from the document production of Patricia Young, with Bates Numbers YOUNG 0085, 0098-0101	14
Excerpts from the transcript of the deposition of Cheryl Barreca (Nov. 11, 2005).	17
Excerpts from the transcript of the deposition of Andrea Palencia (Nov. 4, 2005).	24
Excerpts from the transcript of the deposition of Kenneth A. Vanderwal (Nov. 8, 2005).	25
Excerpts from the transcript of the deposition of Susan Wessels (Nov. 14, 2005).	27
Excerpts from the document production of Gerald Miller, with Bates Numbers GMILLER 0001-0024.	37

I declare under penalty of perjury that the foregoing is true and correct.

By:	/s/ Kristi T. Prinzo
	Kristi T. Prinzo
	Davis Polk & Wardwell
	450 Lexington Avenue
	New York, NY 10017
	Telephone: (212) 450-4000
	Facsimile: (212) 450-3800

Dated: December 1, 2005

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION) MDL NO. 1456) CIVIL ACTION NO. 01-CV-12257-PBS
THIS DOCUMENTS RELATES TO ALL ACTIONS	 Judge Patti B. Saris Chief Mag. Judge Marianne B. Bowler

DECLARATION OF KRISTI T. PRINZO IN SUPPORT OF TRACK 1 DEFENDANTS' OPPOSITION TO PLAINTIFFS' PROPOSED ADDITION OF CLASS REPRESENTATIVES AND PROPOSED CONSOLIDATED ORDER RE: MOTION FOR CLASS CERTIFICATION

I, Kristi T. Prinzo, declare as follows:

- 1. I am an attorney with Davis Polk & Wardwell, counsel for defendant
 AstraZeneca Pharmaceuticals LP in this action. I submit this declaration in support of
 Track 1 Defendants' Opposition to Plaintiffs' Proposed Addition of Class
 Representatives and Proposed Consolidated Order Re: Motion for Class Certification.
- 2. Attached as Exhibit 1 through 37 hereto are true and correct copies of the following:

<u>EXHIBIT</u>	TAB
Plaintiffs' Proposed Consolidated Order Re: Motion for Class Certification (Oct. 17, 2005).	1
Letter from Donald E. Haviland, Jr. to Kristi T. Prinzo (Nov. 29, 2005).	2
Excerpts from the rough transcript of the deposition of Leroy Townsend (Nov. 15, 2005).	3

EXHIBIT	TAB
Choosing a Medigap Policy: A Guide to Health Insurance for People With Medicare 17, 43-44 (2005), available at http://www.medicare.gov/Library/PDFNavigation/PDFInterim.asp?Language=English&Type=PubID=02110 .	4
Declaration of Steven J. Young in Opposition to the Plaintiffs' Motion for Class Certification (Oct. 25, 2004) (submitted in connection with the Track 1 Defendants' Memorandum in Opposition to Class Certification).	5
Letter from John A. Macoretta to James J. Duffy (Nov. 21, 2005).	6
Letter from Steve Berman to D. Scott Wise (Oct. 26, 2005).	7
Excerpts from the transcript of the deposition of David Aaronson, testifying for Susan Aaronson (Nov. 17, 2005).	8
Excerpts from the document production of Susan Aaronson, with Bates Numbers AARON 0046-0152.	9
Excerpts from the transcript of the deposition of James E. Shepley (Nov. 11, 2005).	10
Excerpts from the transcript of the deposition of Robert A. Howe (Nov. 16, 2005).	11
Excerpts from the document production of Robert A. Howe, with Bates Number HOWE 0051 & unstamped pages.	12
Excerpts from the transcript of the deposition of Larry Young, testifying for the Estate of Patricia Young (Nov. 9, 2005).	13
Excerpts from the document production of Patricia Young, with Bates Numbers YOUNG 0085, 0098-0101	14
Letter from TerriAnne Benedetto to Mark Young (Nov. 23, 2005).	15
E-mail from Steve Berman to Mark Lynch (Nov. 14, 2005, 10:16 AM).	16
Excerpts from the transcript of the deposition of Cheryl Barreca (Nov. 11, 2005).	17
Excerpts from the transcript of the deposition of Anna Choice (Nov. 10, 2005).	18
Excerpts from the transcript of the deposition of Joyce Dison (Nov. 9, 2005).	19

<u>EXHIBIT</u>	<u>TAB</u>
Excerpts from the transcript of the deposition of Tracy Garcia (Nov. 15, 2005).	20
Excerpts from the transcript of the deposition of Donna Kendall (Nov. 18, 2005).	21
Excerpts from the transcript of the deposition of Sandra Jean Leef (Nov. 8, 2005).	22
Excerpts from the transcript of the deposition of Constance E. Nelson (Nov. 11, 2005).	23
Excerpts from the transcript of the deposition of Andrea Palencia (Nov. 4, 2005).	24
Excerpts from the transcript of the deposition of Kenneth A. Vanderwal (Nov. 8, 2005).	25
Excerpts from the transcript of the deposition of Pauline Vernick (Nov. 7, 2005).	26
Excerpts from the transcript of the deposition of Susan Wessels (Nov. 14, 2005).	27
Excerpts from the rough transcript of the deposition of Rebecca Anne Hopkins (Nov. 15, 2005).	28
Letter from Jennifer Fountain Connolly to H.B. Roback (Nov. 2, 2005).	29
Letter from Niraj Parekh to Allan Hoffman (Nov. 11, 2005).	30
Letter from Jennifer Fountain Connolly to Niraj Parekh (Nov. 16, 2005).	31
Order dated September 16, 2004 in Walker v. TAP Pharm. Prods., Inc., No. CPM-682-01 (N.J. Super. Ct. Law. Div.).	32
Excerpts from the rough transcript of the deposition of Glenn Randle, testifying on behalf of Sheet Metal Workers National Health Fund (Nov. 17, 2005).	33
Plaintiffs' Motion for Leave to Join Pipefitters Local 537 Trust Funds as a Plaintiff and Proposed Class Representative (filed Nov. 29, 2005).	34
Chemotherapy Drugs, http://www.chemocare.com/bio/adriamycin.asp (last visited Nov. 28, 2005).	35
Letter from James I. Duffy to TerriAnne Benedetto (Nov. 10, 2005).	36

<u>EXHIBIT</u> <u>TAB</u>

Excerpts from the document production of Gerald Miller, with Bates Numbers GMILLER 0001-0024.

37

I declare under penalty of perjury that the foregoing is true and correct.

By: /s/ Kristi T. Prinzo

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Dated: December 1, 2005

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE
LITIGATION

MDL NO. 1456
Civil Action No. 01-12257-PBS

Hon. Patti B. Saris

THIS DOCUMENT RELATES TO
01-CV-12257-PBS AND 01-CV-339

NOTICE OF FILING UNDER SEAL

To: All Counsel of Record

Please take notice that on December 1, 2005, the Track 1 Defendants in the above-captioned matter caused to be filed with the Clerk of the District of Massachusetts, under Seal, the Declaration of Kristi T. Prinzo in Support of the Track 1 Defendants' Opposition to Plaintiffs' Proposed Addition of Class Representatives and Proposed Consolidated Order re: Motion for Class Certification under Seal.

Dated: December 1, 2005

/s/ Kristi T. Prinzo

Kristi T. Prinzo DAVIS POLK & WARDWELL 450 Lexington Avenue New York, NY 10017 212.450.4741 (tel) 212.450.3741 (fax)

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

THIS DOCUMENT RELATES TO

01-CV-12257-PBS AND 01-CV-339

HON. 1456

Civil Action No. 01-12257-PBS

Hon. Patti B. Saris

TRACK 1 DEFENDANTS' MOTION FOR LEAVE TO FILE UNDER SEAL

The Track 1 Defendants, ¹ by their attorneys, hereby move this Court for leave to file the Declaration of Kristi T. Prinzo in Support of the Track 1 Defendants' Opposition to Plaintiffs' Proposed Addition of Class Representatives and Proposed Consolidated Order re: Motion for Class Certification under Seal.

Pursuant to the Protective Order entered by this Court on December 13, 2002 (the "Protective Order") both the parties in the above captioned case and non-party witnesses have designated many documents and other information produced in this litigation as either "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL." The foregoing submission incorporates documents containing information that has been designated "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL." It includes references to contractual terms and pricing data that defendants and non-party witnesses deem highly proprietary in

¹ The Track 1 defendants are: AstraZeneca, the BMS Group, SmithKlineBeecham, d/b/a GlaxoSmithKline, the Johnson & Johnson Group, and the Schering-Plough Group.

nature. Pursuant to paragraph 15 of the Protective Order, any document or pleading containing quotes from or otherwise referencing such information shall be filed under seal.

WHEREFORE, the Track 1 Defendants respectfully request that this Court grant them leave to file the submissions listed above under seal.

Dated: December 1, 2005

/s/ Kristi T. Prinzo

Kristi T. Prinzo DAVIS POLK & WARDWELL 450 Lexington Avenue New York, NY 10017 212.450.4741 (tel) 212.450.3741 (fax)